SEP - 5 2000

K002051 Page 1 of 2

510(k) Summary

This summery is submitted in compliance with 21 CFR 807.92

(a) (1) Submitted by:

Scanditronix Medical AB
Stålgatan 14,
S-754 50 Uppsala
Sweden
Phone no: +46 18 18 07 00
Fax no: +46 18 12 75 52

Contact persons:

Lars Göran Larsson
Phone no: +46 18 18 08 52
or
Eva Larsten
Phone no: +46 18 18 07 88

Date of preparation: 19-June-2000

(2) Trade name of device: InViDos

Common name: Patient Dosimetry Management System

Classification name: (Accessory to) Radionuclide radiation therapy system, §892,5750; X-ray radiation therapy system, §892,5900; and Medical charged-particle radiation therapy system, §892.5050.

(3) Identification of predicate marketed device:

DPD-3 (Scanditronix Medical AB),
FDA K942092/S1, 510(k) July 1994,
DPD-510 (Scanditronix Medical AB)
FDA K925133, 510(k) Jan.1993.
DPD-12PC (Scanditronix Medical AB)
FDA K990734, 510(k) May 1999

(4) Description of the device:

The Scanditronix Medical InViDos Patient Dosimetry Management System is a device similar to DPD-12PC, Direct Patient Dosemeter, FDA K990734, 510(k) May 1999, used for Patient Dosimetry Dosimetry in radiation therapy. It consists of one of the alternative electrometers, 3, 10, single or dual 12 channels, user interface software, semiconductor detectors, detector support, extension cable, communication cable. 3'rd party vendor EPID (Electronic Portal imaging device) can be used as a detector device

(5) Intended uses:

The intended use of InViDos is independent patient specific dosimetry, verifying that the dose to the patient is delivered as planned utilising electrometers, detectors and EPID (Electronic Portal Imaging Devices). InViDos is intended to be used by physicists, therapists, clinicians and other personal in a radiotherapy clinic performing treatment of cancer utilising ionising radiation.

(6) Technological comparison:

The Scanditronix Medical InViDos Patient Dosimetry Management System is a similar device to the predicate device Scanditronix Medical's DPD-12PC. 3'rd party vendor EPID (Electronic Portal imaging device) can be used as a detector device

(b) (1) Non-Clinical tests:

Comparison of operational characteristics for the Scanditronix Medical InViDos Patient Dosimetry Management System and the predicate product show similar results that are suitable for their intended purpose. To minimize potential electrical hazards, Scanditronix Medical adheres to recognized and established industry practice, and all devices are subject to final performance testing. The Scanditronix Medical InViDos, Patient Dosimetry Management System is designed for conformance with IEC 601-1 standards for electrical isolation and leakage current and meets electrical performance standards for CSA and UL. In addition, all semiconductor detectors fulfill the IEC-601-2-9 standard.
The electrometers of Scanditronix Medical InViDos Patient Dosimetry Management System has been tested and found to fulfil the requirements concerning electromagnetic compatibility according to the standard IEC 601-1-2.
Calibration, when used as specified, of EPID has been tested and found to correspond to the actual dose

(2) Clinical tests:

Due to the fact that the system is a quality assurance device in radiation treatment (Patient Dosimetry) not directly involved in the delivery of the treatment radiation, no clinical testing was performed.

(3) Test conclusions:

Testing of operational parameters indicates that the Scanditronix Medical InViDos Patient Dosimetry Management System is safe, it fulfils the intended use and performs as well as or better than the previously released product DPD-12PC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2000

Eva Larsten
Quality Manager
Scanditronix Medical AB
Stalgatan 14
S-754 50 Uppsala
Sweden

Re: K002051
InViDos Patient Dosimetry Management System
Dated: June 29, 2000
Received: July 6, 2000
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Ms. Larsten:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K002051

Device Name: InViDos Patient Dosimetry Management System

Indications for Use:

The InViDos Patient Dosimetry Management System is used for
- independent patient specific dosimetry in radio therapy
- quality control measurements of therapeutic radiation devices

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002051

Prescription Use ✓ OR Over-The -Counter Use_____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)